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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,699	07/27/2006	James Browning	8830-367 (216365)	3780

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EXAMINER	
ELLIS, SUEZU Y	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
04/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,699	BROWNING, JAMES	
	Examiner	Art Unit	
	Suezu Ellis	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9/27/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 27, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39, 48 and 49 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 39, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

With respect to claims 48 and 49, claim language recites the term “and/or”. It is unclear whether the “and/or” is to be in the alternative form.

With respect to claims 48 and 49, claims appear to reference claims 4 and 2, respectively. However, examiner notes that there are no claim 2 and claim 4. Therefore it is unclear which claims applicant is referencing. Please clarify. The scope of the claim is so unclear that the claims will not be treated on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 26, 28, 30, 32, 37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw, Jr. (US 4,233,968).

With respect to claim 25, Shaw, Jr. discloses in Fig. 1, an implantable medicament delivery device (intrauterine device) comprising means for providing controlled delivery of a medicament (col. 4, line 42 – col. 5, line 3), an elongate body having an outer surface, a first end (10) and a second end (8) wherein the second end (8) includes a head portion wherein the head portion is a lateral extension from the longitudinal axis of the elongate body and the head portion allows manipulation and surveillance of the implant (col. 11, lines 24-37). Although the system of Shaw, Jr. is not directed towards an implantable medicament delivery device insertable into the female uterine myometrium, Applicant's claim language does not provide any structural limitations limiting the system to being inserted into the female uterine myometrium -

therefore, the limitation in the preamble of the system as recited is directed towards an intended use of the system, and hence, cannot be given patentable weight.

With respect to claims 26 and 28, Shaw, Jr. discloses the means to provide controlled delivery of the medicament is provided on the body of the implant (head portion) (col. 4, line 65 - col. 5, line 3; col. 11, lines 30-37).

With respect to claim 30, Shaw, Jr. discloses in Fig. 1, the first end having a semi-sharp point.

With respect to claim 32, Shaw, Jr. illustrates in Figs. 1 and 2, the head portion is a substantially flat plate which extends in all radial directions from the second end of the body of the device.

With respect to claim 37, Shaw, Jr. discloses the inclusion of a medicament (col. 4, line 65 - col. 5, line 3).

With respect to claim 39, Shaw, Jr. discloses the medicament is for estrogen dependent proliferative disorder of the pelvis (menorrhagia or metrorrhagia) (col. 4, lines 10-46).

Claims 25, 26, 28, 30, 31, 37, 38, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated Ramwell (US 3,888,975).

With respect to claim 25, Ramwell discloses in Fig. 1, an implantable medicament delivery device comprising means for providing controlled delivery of a medicament (col. 3, line 64 – col. 4, line 20), an elongate body having an outer surface, a first end (12) and a second end (11) wherein the second end (11) includes a head

portion wherein the head portion is a lateral extension from the longitudinal axis of the elongate body and the head portion allows manipulation and surveillance of the implant. Although the system of Ramwell is not directed towards an implantable medicament delivery device insertable into the female uterine myometrium, Applicant's claim language does not provide any structural limitations limiting the system to being inserted into the female uterine myometrium - therefore, the limitation in the preamble of the system as recited is directed towards an intended use of the system, and hence, cannot be given patentable weight.

With respect to claims 26 and 28, Ramwell discloses the means to provide controlled delivery of the medicament is provided in or on the body or head of the implant (col. 4, lines 1-2).

With respect to claim 30, Ramwell discloses in Fig. 1, the first end having a semi-sharp point.

With respect to claim 31, Ramwell discloses the device is absorbable (col. 4, lines 1-4).

With respect to claims 37, 38 and 40, Ramwell discloses the device comprising at least one medicament, wherein the medicament is an anti-inflammatory agent, an anti-microbial agent, or progestins (col. 12, lines 2, 8, 32-36, 43).

With respect to claim 41, Ramwell discloses the cumulative release rate of the medicament is from about 1 day to 30 days or a year (col. 15, lines 45-67).

Claim 43 is rejected under 35 U.S.C. 102(b) as being anticipated by Theeuwes et al. (US 3,916,899).

With respect to claim 43, Theeuwes et al. discloses a method for introducing a medicament into the body of a female mammal comprising the step of inserting an implantable medicament delivery device, the device comprising means capable of providing controlled delivery of a medicament over a period of time into the myometrium (col. 11, lines 1-55).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27, 29 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw, Jr.

With respect to claims 27 and 29, Shaw, Jr. addresses all the limitations of claim 25, however fails to expressly disclose the detailed steps of the implant in use. Nevertheless, since the claim language provides functional language regarding the use of the device, the claim language is considered intended use and cannot be given patentable weight.

With respect to claim 41, Shaw, Jr. addresses all the limitations of claim 25, however fails to expressly discloses the claimed release rate of the medicament.

However, Shaw, Jr. does disclose adjusting the characteristics of the polymer matrix in order to create a desired release rate (col. 4, lines 60- col. col. 5, line 3). Therefore it would have been obvious to one of ordinary skill in the art to modify the release rate depending on the desired application.

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw, Jr. in view of Scommegna (US 3,911,911).

With respect to claims 33 and 34, Shaw, Jr. addresses all the limitations of claim 25, however fails to expressly disclose the inclusion of a retrieval means being on the second end. Scommegna discloses in Fig. 2, using a retrieval means (elongated flexible member) on the second end to insert the device into the uterus (col. 3, lines 33-64). It would have been obvious to one of ordinary skill in the art to include a retrieval means in order to insert the device into the uterus. Examiner notes that the term "retrieval means" is not given significant patentable weight since claim language does not provide any structural limitations regarding the "retrieval means".

Claims 35, 36 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw, Jr. in view of Hoff (US 3,993,058).

With respect to claims 35 and 36, Shaw, Jr. addresses all the limitations of claim 25, however fails to expressly disclose the device having an axial length from 5 mm to 45 mm and a diameter from 0.5 mm to 4 mm. Hoff discloses it is well known for an intrauterine device to have a length of 20-40 mm and a diameter of 1-4 mm. It would

have been obvious to one of ordinary skill in the art to modify the size of the device depending on the desired user comfort and uterine retention.

With respect to claim 40, Shaw, Jr. addresses all the limitations of claims 25 and 37, and further discloses the medicament is a contraceptive, however fails to expressly disclose the contraceptive is a combined oral contraceptive. However, it is well known in the art to utilize combined oral contraceptive drugs with intrauterine devices, as taught by Hoff (col. 4, lines 20-29). It would have been obvious to one of ordinary skill in the art to utilize a combined oral contraceptive in the intrauterine device in order to attain the predictable result of reducing conception.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw, Jr. in view of Gutnick (US 3,913,573).

With respect to claims 42 and 47, Shaw, Jr. addresses all the limitations of claim 25, however fails to expressly disclose the inclusion of an insertion tool. Gutnick discloses in Fig. 7, an insertion tool having an elongate shaft, the shaft having a handle (96) at a first end thereof and a mounting means (end of the tube) at a second opposite end wherein the medicament delivery device (intrauterine contraceptive device) is mountable on the device mounting means of the insertion tool for introducing an intrauterine contraceptive device into the uterus. It would have been obvious to one of ordinary skill in the art to utilize an insertion tool in order to provide a means of inserting the medicament delivery device into the uterus.

Claims 27, 29 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramwell (US 3,888,975).

With respect to claims 27 and 29, Ramwell addresses all the limitations of claim 25, however fails to expressly disclose the detailed steps of the implant in use. Nevertheless, since the claim language provides functional language regarding the use of the device, the claim language is considered intended use and cannot be given patentable weight.

With respect to claim 39, Ramwell addresses all the limitations of claim 37, however fails to expressly disclose the medicament is for estrogen dependent proliferative disorders of the pelvis. However, Ramwell does provides a list of medicaments that can be used, and further discloses other physicologically or pharmacologically active agents can be used (cols. 11 and 12). It would have been obvious to one of ordinary skill in the art to modify the type of medicament used depending on the desired application (e.g. desired disorder to be treated).

Claims 33, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramwell in view of Hoff.

With respect to claim 33, Ramwell addresses all the limitations of claim 25, however fails to expressly disclose the inclusion of a retrieval means being on the second end. Hoff discloses in Fig. 2, using a retrieval means (18) to insert the device into the uterus. It would have been obvious to one of ordinary skill in the art to include a retrieval means in order to insert the device into the uterus. Examiner notes that the

term "retrieval means" is not given significant patentable weight since claim language does not provide any structural limitations regarding the "retrieval means".

With respect to claims 35 and 36, Ramwell addresses all the limitations of claim 25, and further discloses the size of the device can vary (col. 4, lines 59-65). However, the modified Ramwell fails to expressly disclose the device having an axial length from 5 mm to 45 mm and a diameter from 0.5 mm to 4 mm. Hoff discloses it is well known for an intrauterine device to have a length of 20-40 mm and a diameter of 1-4 mm. It would have been obvious to one of ordinary skill in the art to modify the size of the device depending on the desired user comfort and uterine retention, as taught by Ramwell (col. 4, lines 63-65).

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramwell in view of Scommegna.

With respect to claims 33 and 34, the modified Ramwell addresses all the limitations of claim 25, however fails to expressly disclose the inclusion of a retrieval means being on the second end. Scommegna discloses in Fig. 2, using a retrieval means (elongated flexible member) on the second end to insert the device into the uterus (col. 3, lines 33-64). It would have been obvious to one of ordinary skill in the art to include a retrieval means in order to insert the device into the uterus. Examiner notes that the term "retrieval means" is not given significant patentable weight since the claim language fails to provide any structural limitations.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramwell in view of Gutnick.

With respect to claim 42, Ramwell addresses all the limitations of claim 25, however fails to expressly disclose the inclusion of an insertion tool. Gutnick discloses in Fig. 7, an insertion tool having an elongate shaft, the shaft having a handle (96) at a first end thereof and a mounting means (end of the tube) at a second opposite end wherein the medicament delivery device (intrauterine contraceptive device) is mountable on the device mounting means of the insertion tool for introducing an intrauterine contraceptive device into the uterus. It would have been obvious to one of ordinary skill in the art to utilize an insertion tool in order to provide a means of inserting the medicament delivery device into the uterus.

Claims 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes et al.

With respect to claims 44-46, Theeuwes et al. addresses all the limitations of claim 43, however fails to expressly disclose the method of implanting the device and the location of the device being in the myometrium. However, Theeuwes et al. does discloses a medicament is to be delivered to the myometrium (col. 11, lines 37-44). Therefore, one of ordinary skill in the art would appreciate to at least try to implant the device into the myometrium. Examiner notes, the device implanted in the myometrium is considered to be surrounded by the smooth muscle of the myometrial tissue. It would have been obvious to one of ordinary skill in the art to introduce the implant in any

desired location depending on the application (e.g. location where the medicament is to be delivered).

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes et al. in view of Gutnick.

With respect to claim 47, the modified Theeuwes et al. addresses all the limitations of claim 46, however fails to expressly disclose the inclusion of an insertion tool. Gutnick discloses in introducing an intrauterine contraceptive device into the uterus via an insertion tool (Fig. 7). It would have been obvious to one of ordinary skill in the art to utilize an insertion tool in order to provide a means of inserting the medicament delivery device into the uterus.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on (571) 272-4948. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/Sharon E. Kennedy/
Primary Examiner, Art Unit 1615